510(k) SUMMARY of SAFETY And EFFECTIVENESS
ConMed Linvatec

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 510(k) Number K083031.

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

SEP - 5 2008

B. Company Contact

Elizabeth M. Paul
Manager, Regulatory Affairs
(727) 399-5234 Telephone
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C. Device Name

Trade Name: *ConMed Linvatec Microfracture™ Instrument Sterilization Tray*

Common Name: Instrument Sterilization Tray

Classification Name: Sterilization Wrap Containers, Trays and other Accessories

Proposed Class/Device: Class II

Product Code: KCT

Regulation Number: 21 CFR 880.6850

Panel: 880 General Hospital

D. Predicate/Legally Marketed Devices

Paragon Medical Surgical Instrument Delivery Tray
Paragon Medical
510(k) # K0032116

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2008

Ms. Rebecca Roberts
Regulatory Specialist
ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773

Re: K080531
Trade/Device Name: Microfracture™ Instrument Sterilization Tray (MFX-TRAY)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: August 21, 2008
Received: August 22, 2008

Dear Ms. Roberts:

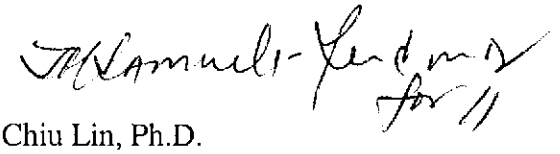
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known) K080531

Device Name Microfracture™ Instrument Sterilization Tray (MFX-TRAY)

Indications for Use

The ConMed Linvatec Microfracture Instrument Sterilization Tray (MFX-TRAY) is a containment device for medical device sterilization. The tray is constructed of metal and plastic with perforations to facilitate steam penetration.

Method	Cycle	Minimum Temperature	Minimum Exposure	Minimum Dry Cycle
Steam (wrapped)	Pre-vacuum	270°F(132°C)	4 minutes	8 minutes
Steam (wrapped)	Gravity	270°F(132°C)	10 minutes	8 minutes

NOTES:
1. Sterilization validation has been conducted in accordance with the requirements of AAMI TIR 12.
2. Validation was conducted using an FDA cleared sterilization wrap with a maximum load of 8.1 lbs. (3.67 kg).

The ConMed Linvatec Microfracture Instrument Sterilization Tray (MFX-TRAY) is intended for use with the following instruments:

REF	Description
MFX-OLT	Microfracture Awl, 0 degrees light
MFX-30LT	Microfracture Awl, 30 degree light
MFX-45LT	Microfracture Awl, 45 degrees light
MFX-90LT	Microfracture Awl, 90 degrees light
MFX-0HV	Microfracture Awl, 0 degrees heavy
MFX-30HV	Microfracture Awl, 30 degrees heavy
MFX-45HV	Microfracture Awl, 45 degrees heavy
MFX-90HV	Microfracture Awl, 90 degrees heavy
MFX-30ANG	Microfracture Awl, Angled, 30 Degrees Heavy
MFX-45CU	Microfracture Awl Currette, 45 Degrees

Sheila A Murphy

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080531